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| APPLICATION NO.             | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------|-------------|----------------------|---------------------|------------------|
| 10/092,730                  | 03/08/2002  | Steven J. Catani     | 15117.0090          | 7337             |
| 23122                       | 7590        | 07/02/2004           | EXAMINER            |                  |
| RATNERPRESTIA               |             |                      | KRISHNAN, GANAPATHY |                  |
| P O BOX 980                 |             |                      | ART UNIT            | PAPER NUMBER     |
| VALLEY FORGE, PA 19482-0980 |             |                      | 1623                |                  |

DATE MAILED: 07/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/092,730

**Applicant(s)**

CATANI ET AL.

**Examiner**

Ganapathy Krishnan

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13-20,22-34,46-49,60-62 and 67-74 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-20,22-34,46-49,60-62 and 67-74 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

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### **DETAILED ACTION**

The amendment filed February 19, 2004 has been received, entered and carefully considered. The following information provided in the amendment affects the instant application:

1. Claims 1-12, 21, 35-45, 50-59, 63-66 and 75-86 have been canceled.
2. Claims 13 and 62 have been amended.
3. Remarks

Claims 13-20, 22-34, 46-49, 60-62 and 67-74 are pending in the case.

The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 46-49, 60-61 and 71-74 are rejected under 35 U.S.C. 102(b) as being anticipated by Antenucci et al, newly cited.

Antenucci et al teach a sucralose concentrate composition (col. 3-4) comprising purified sucralose (col. 2, lines 15-22). This teaching of Antenucci et al is seen to meet the limitations of claims 46-49, 60-61 and 71-74.

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***Claim Rejections - 35 USC § 103***

The allowability of claims 21-34, 46-49, 60-61, 66 and 71-74 indicated in the previous office action has been withdrawn and the following new rejections are made of record.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13-20, 22-34, 62 and 67-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Navia et al (US 5498709) of record in combination with Catani et al (US 5977349) newly cited.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 13-20, 62 and 67-70 are drawn to method of purifying sucralose comprising subjecting a feedstock comprising crude sucralose solution to a non-crystallization purification step to obtain increased purity sucralose solution; performing crystallization to obtain crystalline sucralose, recycling at least a portion of the mother liquor to the said feedstock and performing at least three additional crystallizations to obtain a further purified sucralose; wherein the additional

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recrystallizations are performed 3-5 to times and more than five times; wherein in a dependent claim the mother liquor from any crystallization step is recycled to an earlier crystallization stage; wherein the method is performed as a batch operation; wherein the non-crystallization step is selected from liquid-liquid extraction, extractive precipitation, chromatography and precipitation followed by solvent washing; a method of purifying sucralose from a crude sucralose solution comprising performing a chromatographic purification followed by crystallization procedure.

Navia et al's invention is drawn to production of sucralose. Navia et al teach steam stripping of crude sucralose solution followed by extraction with an appropriate solvent (non-crystallization purification steps) and then crystallization of the increased purity sucralose to obtain a more pure crystalline sucralose. The mother liquors may be used for recycle to obtain additional material (see col. 10, lines 9-31). Navia et al also teach that once crude sucralose has been recovered the product can be purified by crystallization and recrystallization until the desired purity level is reached (see col. 6, line 64 through col. 7, line 4).

Catani et al teach the chromatographic purification of sucralose and at least one additional component from a mixture of chlorinated sucroses (abstract; col. 2, line 55 through col. 3, line 4; col. 6, line 57 through col. 8, line 17). The process can be performed on the actual process stream that includes other impurities including metal and alkyl ammonium salts and can also be performed in a pulse, continuous-pulse or continuous mode. Catani also suggests that the absorbent technology of their invention can be used as yield-enhancing adjuncts to crystallization or derivatization approaches (col. 6, lines 43-45).

Based on these teachings of Navia and Catani et al it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine a chromatographic (non-crystallization) purification step with a crystallization step in a method to purify sucralose from any crude sucralose solution since the two techniques are taught individually in the prior art for the purification of sucralose.

The difference seen between Navia's process and the instant invention is that the instant invention uses 3-5 or more than five recrystallization steps to purify sucralose whereas Navia et al disclose that recrystallization can be performed till desired level of purity is reached.

Based on this disclosure of Navia et al and the fact that crystallization of sucralose is relatively easier (col. 2, lines 42-43) it would have been obvious to one of ordinary skill in the art at the time the invention was made to use sequential recrystallization steps to purify sucralose since it is an ideal art tested method of increasing the purity level of sucralose.

It is logical to combine two methods of purification into a single method for the same purpose since such a combination would lead to a product of very high purity.

### ***Conclusion***

Claims 13-20, 22-34, 46-49, 60-62 and 67-74 are rejected.

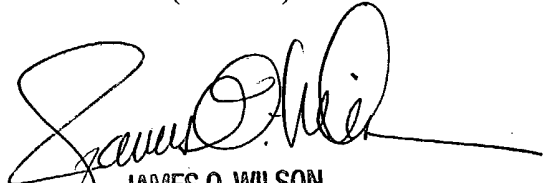
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GK



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